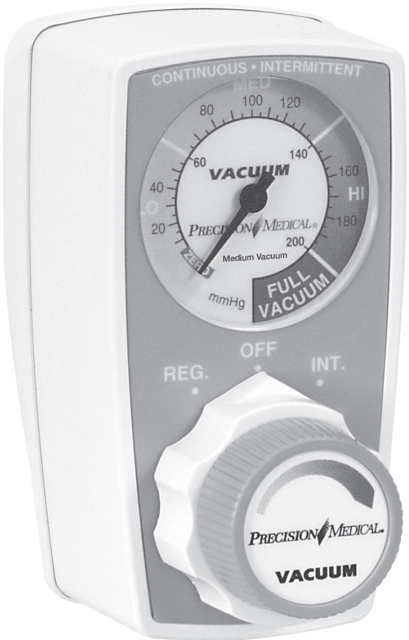
USER MANUAL

VACUUM REGULATOR

PEDIATRIC INTERMITTENT

MODEL SERIES: PM3300 *(shown)*
PM3400



SAVE THESE INSTRUCTIONS

⚠CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician.

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CONTENTS

RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *Vacuum Regulator* from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The devices are intended to control and show the amount of vacuum from a central vacuum system used in various medical suctioning procedures.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the *Vacuum Regulator*. This is provided for your safety and to prevent damage to the Vacuum Regulator. If you do not understand this manual, DO NOT USE the Vacuum Regulator and contact your Provider.

EXPLANATION OF ABBREVIATIONS

l/min	Liters Per Minute
mmHg	Millimeters of Mercury
inHg	Inches of Mercury
kPa	Kilopascal

SAFETY INFORMATION - WARNINGS AND CAUTIONS

⚠WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**

⚠WARNING

- **DO NOT** use this Vacuum Regulator for anything other than its Intended Use. Personal injury and/or damage to Regulator may result from misuse.
- Only personnel instructed and trained in its use should operate this Vacuum Regulator.

SPECIFICATIONS

GAUGE RANGE:

PM3300:	0 - 200 mmHg - Full Vacuum
*PM3300E:	0 - 200 mmHg (0 - 26 kPa)
*PM3300EHV:	0 - 300 mmHg (0 - 40 kPa)
PM3300HV:	0 - 300 mmHg - Max Vacuum
PM3400:	0 - 150 mmHg
*PM3400E:	0 - 150 mmHg (0 - 20 kPa)

*Counterclockwise direction

GAUGE ACCURACY:

Analog: ± 5% of MAX

Digital/Analog, Dual Gauge:

Digital Display: ± 1% of Full Scale

Analog Gauge: ± 5% of MAX within ref. Indicator

VACUUM PORTS: 1/8 NPT Female

MODES:

REG. - (Regulated) provides an adjustable, continuous vacuum level

OFF - No Vacuum

INT. - (Intermittent) provides an adjustable vacuum level that cycles between ON and OFF

FLOW:

Models	***Mode***	***Max Flow***
PM3300:	REG	51 l/min
PM3400:		50 l/min

MAXIMUM FLOW IS OBTAINED WITH A VACUUM SOURCE OF 21" Hg (71.1 kPa)

MAXIMUM VACUUM:

PM3300: REG. Mode @ Full Vac-396 mmHg (53 kPa)

PM3300HV: REG. Mode @ Max Vac-396 mmHg (53 kPa)

PM3400: Restricted to 170 mmHg ± 10 mmHg (1.3 kPa)

INTERMITTENT CYCLE TIME: Factory set at sixteen (16) seconds ON and eight (8) seconds OFF ± 2

Operating Environmental Limits: 0°F to 122°F (-18°C to 50°C)

Recommended Environmental Operating Limits: 55°F to 85°F (13°C to 29°C)

Storage Environmental Limits:

Temperature Range: -4°F to 140°F (-20°C to 60°C)

Humidity: Max 95% Noncondensing

Battery: 3 Volt Lithium, ½ AA

Specifications are subject to change without prior notice.

OPERATING INSTRUCTIONS

CAUTION

Inspect the Vacuum Regulator for visual damage before use, DO NOT USE if damaged.

NOTE:
- Overflow protection should be used with the Vacuum Regulator. (i.e. Filter, Vac Trap, Canister equipped with float shutoff).
- Gauges operate independently; if the digital gauge fails, the analog gauge will still function.

1. Turn the Selector Knob to the "OFF" position.
2. Attach the Vacuum Regulator to the vacuum source.
   A. REG MODE (Regulated Mode) **ALL MODELS**
      1. Turn the Selector Knob to the "REG." position.
      2. Block the bottom port of the Regulator.
      3. Using the Regulator Knob, set the desired vacuum.
         To **INCREASE** vacuum - Turn Knob **CLOCKWISE**
         To **DECREASE** vacuum - Turn Knob **COUNTERCLOCKWISE**
   B. INT. MODE (Vacuum cycles ON and OFF.)
      1. Turn the Selector Knob to the "REG." position, to select desired vacuum level.
      2. Turn the Selector Knob to the "INT." position.
         NOTE: Intermittent cycles starts in the OFF phase, therefore a delay occurs before the intermittent cycle begins.
3. Turn the Selector Knob to the "OFF" position to turn the Regulator off.

⚠WARNING

- ALWAYS confirm vacuum setting prior to performing procedure.
- When turning the Vacuum Regulator to "REG." or "INT." from any position, the vacuum level will return to its previously regulated setting.
- **Full Line Vacuum is present between settings.**
- Vacuum levels will remain the same when switching from one mode to the other.

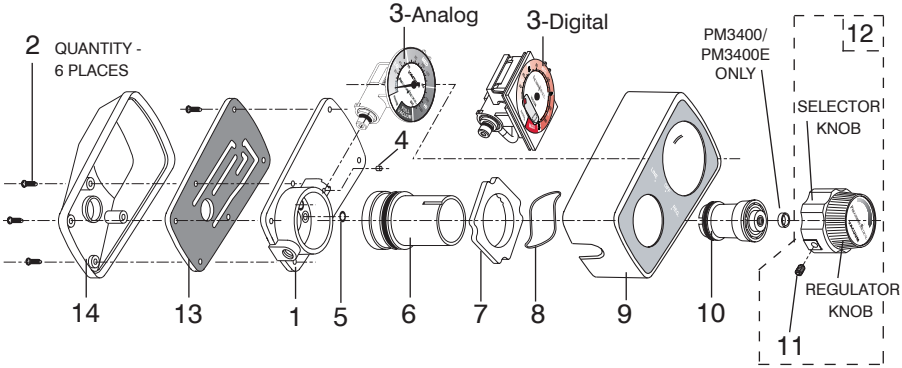
⚠CAUTION

DO NOT operate the Vacuum Regulator when the collection canister is "full". This may cause loss of vacuum and damage to the Vacuum Regulator. This will **void the warranty**.

PARTS DESCRIPTION

⚠CAUTION

Missing or illegible labels must be replaced, contact Precision Medical, Inc.



PARTS LIST

No.	Description	PM3300	PM3400
1	Housing Assembly	502102	
2	Screw	503956	
3	Analog Gauge Assembly Analog Gauge Assembly (Export E) Analog Gauge Assembly (HV) Digital Assembly Digital Assembly (HV) Digital Assembly (Export E) Digital Assembly Export E (HV)	503694 503923 504309 505244 (0-200 mmHg) 505392 (0-300 mmHg) 506036 506038	503826 504225 505391 (0-150 mmHg) 506034
4	Snubber	1396	
5	O-ring	502231	
6	Selector Assembly	1805	
7	Index Ring	502685	
8	Wave Spring Washer	1614	
9	Case Assembly	1827	
10	Regulator Module Assembly	1567 **(*505962)**	1567
11	Set Screw	1391	
12	Control Knob Assembly	502100	
13	Timing Module	502103	
14	Rear Case	1831	

*** HV MODELS ONLY** (PM3300HV)

REPAIR KITS

	Analog Part#	Digital Part#
PM3300 / PM3300D Vac Reg	RK6300	RK6300D
PM3300HV / PM3300DHV Vac Reg	RK6300HV	RK6300DHV
PM3300E / PM3300DE Vac Reg	RK6300E	RK6300DE
PM3300EHV / PM3300DEHV Vac Reg	RK6300EHV	RK6300DEHV
PM3400 / PM3400D Vac Reg	RK6400	RK6400D
PM3400E / PM3400DE Vac Reg	RK6400E	RK6400DE

DISASSEMBLY INSTRUCTIONS

(Reference “PARTS DESCRIPTION”)

1. Loosen the Set Screw (Item # 11) in Selector Knob.
2. Pull the Control Knob Assembly (Item # 12) away from case. (The Regulator Module (Item # 10) is threaded onto the Control Knob Assembly.)
3. Remove the screws (Item # 2) from the back of the product.
4. Remove the Rear Case (Item # 14) by pulling away from product.
5. Remove screws (Item# 2) from the top of the Timing Module.
6. Remove the Timing Module (Item# 13) by pulling away from the Housing Assembly (Item# 1).
7. Separate the Case Assembly (Item# 9) by pulling it away from the Housing Assembly (Item# 1).
8. Remove the Selector Assembly (Item# 6) by pulling it away from the Housing Assembly (Item# 1).
9. Remove the Gauge Assembly (Item# 3).

ASSEMBLY INSTRUCTIONS

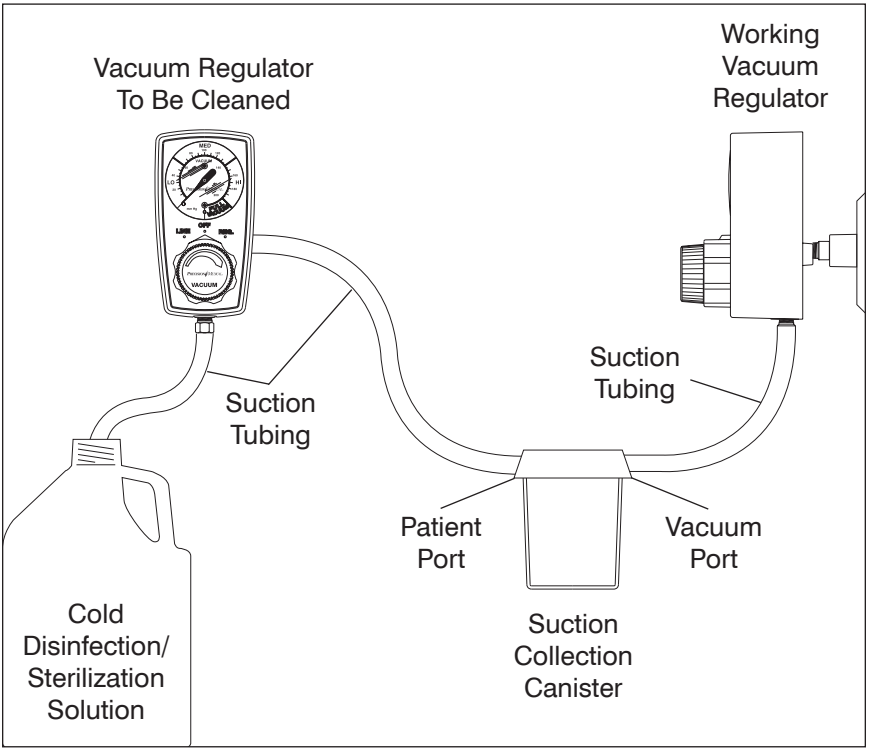
1. To assemble, perform the “DISASSEMBLY INSTRUCTIONS” in reverse order.

   NOTE: • Ensure the Selector Assembly is inserted with the groove in the 12 o’clock position.

   • Ensure tabs and slots on various components are properly aligned and engaged when reassembling.
2. Lubricate all O-rings and cavities with Vacuum grease (part# 1775) supplied in the Vacuum Regulator Repair Kit.
3. Repeat steps 1 through 3 of “OPERATING INSTRUCTIONS”.
4. Prior to returning Vacuum Regulator to service verify accuracy of gauge.

VACUUM REGULATOR CLEANING ILLUSTRATION

(Cleaning/Decontamination Instructions on **page 8)**



⚠CAUTION

- **DO NOT** autoclave or immerse in liquid.
  This will cause damage to the Vacuum Regulator and will **void the warranty**.
- If Vacuum Regulator becomes internally contaminated, warranty is voided, DO NOT send back to Precision Medical, Inc. for repair. Follow your facilities contaminated equipment protocol.
- This Vacuum Regulator contains magnetic, ferrous material that may affect the results of an MRI.
- Be sure all connections are tight and leak free.

CLEANING / DECONTAMINATION (As needed)

1. Attach a working Vacuum Regulator with a continuous regulated mode to a minimum vacuum source of 15 inHg.
2. Mix cold disinfection / sterilization solution according to its manufacturer's directions.
3. Connect tubing as shown in Cleaning Illustration on previous page.
4. Turn the working Vacuum Regulator on to a continuous regulated mode.
5. Adjust the vacuum to a minimum of 120 mmHg.
6. Set the Vacuum Regulator to be cleaned to the "REG ." mode, and set at 100 mmHg.
7. Allow cold disinfection / sterilization solution to pass through and collect in Suction Canister. Procedure should continue for time recommended by the manufacturer of the cold disinfection / sterilization solution for the desired level of disinfection or sterilization.
8. Turn the Vacuum Regulator to be cleaned to the "INT." mode.
9. Allow remaining cold disinfection / sterilization solution to pass through and collect in Suction Canister.
10. Set working Vacuum Regulator to its maximum vacuum setting.
11. Thoroughly dry the internal components by drawing maximum vacuum through the Regulator to be cleaned for at least 30 seconds in both "REG." and "INT." modes.

NOTE: If it is not possible to pass cold disinfection / sterilization solution through the Regulator, then the passageways are totally blocked and disassembly of the Regulator is required. Be sure to follow your facilities' Biohazard protocol.

MAINTENANCE

Before each use; visually inspect Vacuum Regulator for any sign of damage, DO NOT USE if damaged.

RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

Manuals available on our website; www.precisionmedical.com.

DISPOSAL INSTRUCTIONS

Dispose of the Vacuum Regulator in accordance with the local regulations.

Please Recycle

⚠WARNING

Product should be cleaned before being disposed of. Potential for Biohazard.

TROUBLESHOOTING

If the Vacuum Regulator fails to function, consult the Troubleshooting Table below. If problem cannot be solved, consult your Provider.

Problem	Probable Cause	Remedy
No vacuum at bottom port (gauge at zero)	1. Regulator turned "OFF" 2. Loose connection 3. No vacuum to Regulator 4. Clogged vacuum Port	1. a. Turn selector knob 1. b. Adjust Regulator knob 2. Tighten connection 3. Connect to a known working vacuum source 4. Disassemble & clean
No vacuum at bottom port (gauge showing vacuum)	Clogged Regulator	Disassemble & clean
Vacuum at bottom port (No reading on gauge when port is blocked)	Defective Gauge	Replace Gauge
Gauge will not return to zero	1. Clogged Snubber 2. Damaged Regulator Module 3. Defective Gauge	1. Replace Snubber 2. Replace Regulator Module 3. Replace Gauge
Vacuum Regulator erratic	1. Dirty Regulator Module 2. Defective Regulator Module	1. Disassemble & clean, Lubricate O-ring 2. Replace Module
Stiff movement of Selector Knob	1. Dirty Regulator Module and/or Selector Module	1. Disassemble & clean, Lubricate O-rings
No Intermittent (INT.) cycle	1. Improper mode selected 2. Defective Timing Module	1. Turn Selector Knob to "INT." mode 2. Replace Timing Module
No digital display	Dead Battery	Replace Battery

LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Medical Vacuum Regulator (the Product) will be free of defects in workmanship and/or material for the following period:

Ten (10) years from date of shipment.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representative of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

DECLARATION OF CONFORMITY

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REF

Vacuum Regulators:
PM3300E, PM3300E-P, PM3300EHV, PM3300DE, PM3300DE-G, PM3300DE-MG, PM3300DE-Y, PM3300DEHV, PM3300DEHV-MG, PM3400E, PM3400DE

Classification: IIa

Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We herein declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premises of the manufacturer and the notified body.

Directives: General Application Directives: (MDD) Medical Device Directive, Council Directive 93/42/EEC of 14 June 1993 Annex II, 3 Concerning Medical Devices of The European Parliament.

Applied Standards: *EN 980, EN 1041, EN ISO 14971, EN ISO 10079-3*

Notified Body: TÜVRheinland LGA Products GmbH CE 0197

Address: Tillystrasse 2, 90431 Nurnberg, Germany

Certification Registration No's: HD60019110 0001
Date of Expiry: 03/08/2012

Devices already manufactured: S/N traceability Device History Records

Validity of DOC: 11/01/11 to Date of Expiry

Manufacture Representative: Quality Manager

Position: Quality Systems/ISO Representative

Date of Issue: 7/18/07

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